THE HONORABLE MARSHA J. PECHMAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KENNETH McGUIRE, On Behalf of Himself and All Others Similarly Situated,

Plaintiffs,

v.

DENDREON CORPORATION, et al.,

Defendants.

CASE NO.: C07-800-MJP

Consolidated Class Action

DECLARATION OF ELIZABETH SMITH IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT IN *MCGUIRE V. DENDREON* AND *MOUNTANOS V. DENDREON*

Note on Motion Calendar: July 30, 2010

ORAL ARGUMENT REQUESTED

This document relates to:

All Actions.

WILLIAM MOUNTANOS, PETER MOUNTANOS, JAMES RYE, and TYRONE REMINGA,

Plaintiffs,

v.

DENDREON CORPORATION, a Delaware Corporation, MITCHELL GOLD, and DAVID URDAL,

Defendants.

CASE NO.: C09-426-MJP

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I, Elizabeth Smith, declare as follows:

1. I am the Vice President of Regulatory Affairs for Dendreon Corporation ("Dendreon" or "Company"). I make this declaration in support of Defendants' Motion for Summary Judgment in *McGuire v. Dendreon* and *Mountanos v. Dendreon*, filed concurrently herewith. I am familiar with the facts set forth herein and could and would testify thereto if necessary.

2. As the Vice President of Regulatory Affairs, I am responsible for managing Dendreon's communications with the FDA. In this role, I was part of the management team for the 2007 Pre-License Inspection ("PLI") by the FDA of Dendreon's New Jersey manufacturing facility.

3. Based on my industry knowledge and experience, and the expertise and experience of other members of the Dendreon leadership team, I know that following a facility inspection, the FDA typically issues a Form 483, containing the inspectors' observations about the manufacturing facility. Thus, I anticipated that Dendreon would likely receive a Form 483 after the PLI, no matter how well prepared we were to host the inspection.

4. During every inspection, FDA inspectors will voice their comments and concerns, make recommendations for improvement, and ask the company difficult questions. However, based on my personal observations and the comments made by other Dendreon staff members, I thought that the interactions between FDA inspectors and Dendreon employees were positive and productive, and that Dendreon staff professionally and efficiently responded to a multitude of requests for information from, and questions posed by, the FDA inspectors.

5. The results of the PLI were presented in the Form 483 that the FDA issued to Dendreon at the close of the inspection. *See* Ex. 22 (2007 Form 483). In evaluating the Form 483, I thought that Dendreon could address all the observations in a timely and effective way, and that none of them were "showstoppers" that would impede the FDA's approval of Provenge. As a result, I considered the PLI to be a successful inspection.

6. During the course of the PLI, and following the conclusion of the inspection and the receipt of the Form 483, I had regular discussions with my supervisor, Dr. David Urdal,

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Dendreon's Chief Scientific Officer and Dr. Mitchell Gold, Dendreon's Chief Executive Officer. During these discussions, I shared my impressions of the PLI and my thoughts about the Form 483, all of which supported the conclusion that Dendreon had hosted a good inspection. My evaluation was consistent with the opinions that I heard expressed by Dr. Urdal himself, as well as by other members of the Dendreon leadership team.

7. Dendreon responded to the Form 483 with a comprehensive response that we sent to the FDA within ten business days of the PLI, containing an action plan that we thought would resolve all of the observations in advance of the FDA's May 15, 2007 action date. *See* Ex. 26 (Dendreon's March 2, 2007 response to the Form 483 observations).

8. I believed that the FDA's actions leading up to the Advisory Committee indicated a willingness to work with Dendreon to address any outstanding issues, including those concerning the Form 483 observations, so that approval would not be delayed. For example, the FDA requested weekly conference calls to ensure that there would be a regular forum in which to resolve issues. Ex. 25 (email reflecting request for weekly conference calls). Through these calls, as well as through other communications and correspondence, Dendreon and FDA representatives discussed and addressed various issues that arose during the FDA's review of the Provenge BLA.

9. During a March 23, 2007 conference call, Dr. Keith Wonnacott, the FDA's lead product reviewer for the Provenge BLA, indicated that Dendreon's proposed responses to eight of the nine Form 483 observations would constitute only minor amendments to the BLA. I interpreted this comment to mean that we were on a path toward resolving all of these observations without any delay of the PDUFA date. Dr. Wonnacott also indicated during this conference call that Dendreon's initial proposal to resolve Observation 1 of the Form 483, which included the submission of additional data to the FDA, could constitute a major amendment to the BLA, which might delay the PDUFA date by three months. In response, I indicated that Dendreon wanted to keep the May 15, 2007 PDUFA date in place if possible, and offered a proposal that would allow for approval based on existing validation data. According to the terms

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of our proposal, the FDA would approve our BLA with an initial limit on manufacturing capacity, which would be lifted following approval after we had submitted additional data. Dr. Wonnacott and the other FDA representatives on the call indicated their openness to our proposal, and Dr. Wonnacott indicated that our proposed schedule for the consideration of additional validation data would probably be acceptable. He said that they would be prepared to discuss the details of the proposal after the March 29, 2007 Advisory Committee meeting. *See* Ex. 29 (Dendreon minutes from March 23, 2007 conference call); Ex. 32 (FDA minutes from March 23, 2007 conference call); Ex. 31 (notes by Dendreon's Karen Krstulich from March 23, 2007 conference call); Ex. 30 (notes by Dendreon's Mary Coon from March 23, 2007 conference call).

10. I left the March 23, 2007 conference call with a positive feeling that the FDA was continuing to work with Dendreon in order to resolve any issues in advance of the PDUFA date. In my previous and subsequent dealings with Dr. Wonnacott, I believe that he has always been forthright with Dendreon, and it was significant that he did not tell Dendreon that any of the issues in the Form 483 were not resolvable before the PDUFA date, but instead indicated that the FDA wished to engage in continuing discussions to come to a final resolution.

11. The accuracy of my impressions from the March 23, 2007 conference call were confirmed when, during the April 4, 2007 conference call, the FDA asked Dendreon if it would agree to a limited initial manufacturing license that could be supported with existing validation data. *See* Ex. 49 (Dendreon minutes from April 4, 2007 conference call); Ex. 48 (FDA minutes from April 4, 2007 conference call). During this conference call and another call on April 23, 2007, Dendreon and the FDA resolved all of the details necessary to address Observation 1 in a way that would allow for approval of Provenge by the PDUFA date, and provide a path toward an unlimited license within a short period of time after approval. *See* Ex. 50 (minutes from April 23, 2007 conference call).

12. After Dendreon received a Complete Response Letter on May 8, 2007, I contacted Dr. Wonnacott to gain more insight into the reasons for the Complete Response Letter, and

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whether there was anything that Dendreon could have done differently. Specifically, I asked him about the seven CMC items listed in the Complete Response Letter, and why any open issues in regard to these items had not been communicated to Dendreon before the letter was issued. Dr. Wonnacott said that none of the CMC issues, including item 1 related to inspectional issues, had precluded FDA approval. He said the Complete Response Letter was issued because of the FDA's concerns over the sufficiency of Dendreon's clinical data, and that the FDA did not attempt to address the remaining questions about CMC issues once the decision not to approve Provenge had been made. At that point, Dr. Wonnacott said, the FDA decided to list these concerns in the Complete Response Letter. If the CMC issues had been the only issues remaining in advance of approval, he said that they would have been handled differently – either addressed with the Company, or listed as post-approval commitments in an approval letter.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge. Executed in Seattle, WA, on June 21, 2010.

Elizabeth Smith

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who receive CM/ECF notification.

Dated: June 21, 2010

s/ Barry M. Kaplan
Barry M. Kaplan, WSBA#8661

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